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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,151	01/17/2001	Gilbert R. Gonzales	UNSP/ 04	6299
26875	7590	12/06/2005	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/765,151	<b>Applicant(s)</b> GONZALES ET AL.	
	<b>Examiner</b> Anu Ramana	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-19, 21-23 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 10, 11 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 and 15, 17-19, 22, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brilliant (US 3,309,274).

Brilliant discloses an orally administrable composition having a marker at a sufficient concentration to cause contact coloration of at least a portion of the mucous membrane of an oral cavity (col. 1, lines 36-41, col. 2, lines 23-72, col. 3, lines 1-26, col. 4, lines 9-75 and col. 5, lines 15-26).

With regard to the limitation, "the half-life of said marker being comparable to the half-life of said composition," the dye of the Brilliant composition stains the oral cavity for a period after ingestion of the composition and thus has a half-life "comparable" to the half-life of the composition.

The method steps of claims 1-7, 9 and 28 are inherently performed when the Brilliant composition is utilized to diagnose and treat oral conditions of a patient, such as skin lesions.

Claims 1, 4, 9, 12-15, 17-19 and 22, 23 and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al. (US 3,723,613).

Block et al. disclose an orally administrable composition with multiple markers (FDC Red No. 3, FDC Green No. 3) that cause contact coloration of at least a portion of the mucous membrane of a patient (col. 2, lines 17-24, col. 3, lines 60-68 and col. 4).

With regard to the limitation, "the half-life of said marker being comparable to the half-life of said composition," the dye of the Brilliant composition stains the oral cavity for

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a period after ingestion of the composition and thus has a half-life "comparable" to the half-life of the composition.

The method steps of claims 1, 4, 9, 12-14 and 28 are inherently performed when the Block et al. composition is utilized for diagnosis and control of plaque deposits (col. 2, lines 38-55).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brilliant (US 3,309,274).

Brilliant discloses all elements of the claimed invention except for a fluorescent dye such as carmine red.

Carmine red is a well-known fluorescent dye.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted carmine red as a fluorescent pigment for FD&C Red No. 3 in the Brilliant composition, wherein so doing would amount to mere substitution of one functionally equivalent dye for another within the same art and the selection of any of these dyes would work equally well in the claimed invention.

The method steps of claim 8 are rendered obvious by the above discussion.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al. (US 3,723,613) in view of Porter et al. (US 4,643,894).

Block et al. disclose that their composition can be in the form of a chewable tablet, liquid concentrate etc.

It is well known to provide color to tablets by providing color coatings, as evidenced by Porter et al.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a color coating to the surface of the Block et al. composition when provided as a tablet or pill since it was well known in the art to provide color to a tablet in the form of a coating.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brilliant (US 3,309,274) in view of Porter et al. (US 4,643,894).

Brilliant discloses that his composition can be in the form of a pellet.

It is well known to provide color to pellets or tablets by providing color coatings, as evidenced by Porter et al.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a color coating to the surface of the Block et al. composition when provided as a tablet or pill since it was well known in the art to provide color to a tablet in the form of a coating.

### ***Response to Arguments***

The Examiner has carefully considered applicant's arguments submitted under "REMARKS" in the response filed on September 2, 2005.

Applicants' arguments against the rejections of claims 1 and 15 under 35 USC 102(b) as being anticipated by Brilliant are not persuasive because Brilliant clearly discloses that unhealthy tissues such as gingival aberrations in the oral cavity are stained by fluorescent dyes (col. 1, lines 62-72 and col. 2, lines 1-19). It is the Examiner's position that gingival aberrations include diseased mucous membranes. Further, Brilliant discloses FD&C Red No. 3 being claimed by the Applicant. It is also the Examiner's position that use of FD&C Red No. 3, a dye well known for its property of coloring oral tissues in an orally administrable composition would result in coloring of oral tissues whether desirable or not.

Applicants' arguments against the rejections of claims 1 and 15 under 35 USC 102(b) as being anticipated by Block et al. are not persuasive because Block et al. clearly disclose that the dye of their composition fades quickly from teeth and tissues (clearly including the mucous membrane) (col. 3, lines 55-58), indicating that oral tissues, including mucous membranes, are stained by the dye. Further, Block et al. disclose dyes, FD&C Blue No. 1, FD&C Green No. 3 and FD&C Red No. 3 being claimed by the Applicant. The use of the above dyes well known for their property of coloring oral tissues in an orally administrable composition would result in coloring of oral tissues whether desirable or not.

Applicants' arguments against the rejections of claims 8 and 21 under 35 USC 103(a) as being unpatentable over Brilliant and the rejection of claim 16 as being unpatentable over Block et al. in view of Porter are not persuasive because Brilliant and Block et al. clearly disclose contact coloration as discussed above.

### ***Allowable Subject Matter***

Claims 10, 11 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuadha Ramana*  
December 2, 2005

  
EDUARDO G. ROBERT  
PRIMARY EXAMINER